

113 JUN 2005

10/507,399

PTO/SB/01 (08-03)

Approved for use through 07/31/2006. OMB 0651-0032

U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

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# DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☐ Declaration  
Submitted  
With Initial  
Filing

OR

☒ Declaration  
Submitted after Initial  
Filing (surcharge  
(37 CFR 1.16 (e))  
required)

Attorney Docket Number

DRF 3.3-010

First Named Inventor

Rajender Kumar Potlapally

COMPLETE IF KNOWN

Application Number

10/507,399

Filing Date

September 13, 2004

Art Unit

Examiner Name

I hereby declare that:

Each inventor's residence, mailing address, and citizenship are as stated below next to their name.

I believe the inventor(s) named below to be the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

NOVEL CRYSTALLINE FORM OF 5-[4-[[3-METHYL-4-OXO-3,4-DIHYDROQUINAZOLIN-2-YL]  
METHOXY]BENZYL]THIAZOLIDINE-2,4-DIONE POTASSIUM SALT

(Title of the Invention)

the specification of which

☐ is attached hereto

OR

☒ was filed on (MM/DD/YYYY) March 14, 2003 as United States Application Number or PCT International

 Application Number PCT/IB03/00935 and was amended on (MM/DD/YYYY) September 13, 2004 (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				Yes	No
180/MAS/2002	India	March 15, 2002	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

[Page 1 of 2]

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 21 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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**DECLARATION — Utility or Design Patent Application**Direct all correspondence to: ☒ Customer Number: 45776 OR ☐ Correspondence address below

Name

Address

City

State

ZIP

Country

Telephone

Fax

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

**NAME OF SOLE OR FIRST INVENTOR:**☐ A petition has been filed for this unsigned inventor

Given Name

(first and middle (if any)) Rajender Kumar

Family Name

or Surname PotlapallyInventor's  
SignatureRajender KumarDate 22/3/05

Residence: City

State

Country

Citizenship

HyderabadA.P.IndiaIndia

Mailing Address

Bollaram Road, Miyapur

City

State

ZIP

Country

HyderabadA.P.500 016India**NAME OF SECOND INVENTOR:**☐ A petition has been filed for this unsigned inventor

Given Name

(first and middle (if any)) Raju

Family Name

or Surname SrisillaInventor's  
SignatureS. RajuDate 22/3/05

Residence: City

State

Country

Citizenship

HyderabadA.P.IndiaIndia

Mailing Address

Bollaram Road, Miyapur

City

State

ZIP

Country

HyderabadA.P.500 016IndiaAdditional inventors or a legal representative are being named on the 1 supplemental sheet(s) PTO/SB/02A or 02LR attached hereto.

**DECLARATION****ADDITIONAL INVENTOR(S)**

Supplemental Sheet

Page 1 of 1

<b>Name of Additional Joint Inventor, if any:</b>		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Ramabhadra Sarma		Mamillapalli	
Inventor's Signature <i>K.P.N. Sarma</i>		Date <i>22/3/05</i>	
Residence: City <u>Hyderabad</u>	State <u>A.P.</u>	Country <u>India</u>	Citizenship <u>India</u>
Mailing Address <u>Bollaram Road, Miyapur</u> <i>IND.</i>			
Mailing Address			
City <u>Hyderabad</u>	State <u>A.P.</u>	Zip <u>500 016</u>	Country <u>India</u>
<b>Name of Additional Joint Inventor, if any:</b>		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Om Reddy		Gaddam	
Inventor's Signature		Date	
Residence: City <u>Hyderabad</u>	State <u>A.P.</u>	Country <u>India</u>	Citizenship <u>India</u>
Mailing Address <u>Bollaram Road, Miyapur</u>			
Mailing Address			
City <u>Hyderabad</u>	State <u>A.P.</u>	Zip <u>500 016</u>	Country <u>India</u>
<b>Name of Additional Joint Inventor, if any:</b>		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Inventor's Signature		Date	
Residence: City	State	Country	Citizenship
Mailing Address			
Mailing Address			
City	State	Zip	Country

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 21 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

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**DECLARATION****ADDITIONAL INVENTOR(S)**  
Supplemental SheetPage 1 of 1

<b>Name of Additional Joint Inventor, if any:</b>		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Ramabhadra Sarma		Mamillapalli	
Inventor's Signature		Date	
Residence: City Hyderabad	State A.P.	Country India	Citizenship India
Mailing Address Bollaram Road, Miyapur			
Mailing Address			
City Hyderabad	State A.P.	Zip 500 016	Country India
<b>Name of Additional Joint Inventor, if any:</b>		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Om Reddy		Gaddam	
Inventor's Signature <i>Om Reddy</i>		Date <i>29/3/05</i>	
Residence: City Hyderabad	State A.P.	Country India	Citizenship India
Mailing Address Bollaram Road, Miyapur <i>-IND</i>			
Mailing Address			
City Hyderabad	State A.P.	Zip 500 016	Country India
<b>Name of Additional Joint Inventor, if any:</b>		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Inventor's Signature		Date	
Residence: City	State	Country	Citizenship
Mailing Address			
Mailing Address			
City	State	Zip	Country

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 21 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

13 JUN 2005

10/50/399

PTO/SB/80 (11-04)

Approved for use through 11/30/2005. OMB 0851-0035

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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**POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO**

I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(b).

I hereby appoint:



Practitioners associated with the Customer Number:

45776

OR



Practitioner(s) named below (if more than ten patent practitioners are to be named, then a customer number must be used):

Name	Registration Number	Name	Registration Number

as attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignment documents attached to this form in accordance with 37 CFR 3.73(b).

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(b) to:



The address associated with Customer Number:

45776

OR

<input type="checkbox"/> Firm or Individual Name			
Address			
City	State	Zip	
Country			
Telephone			Fax

Assignee Name and Address:

Dr Reddy's Laboratories Limited


7-1-27 Ameerpet

Hyderabad 500 016, Andhra Pradesh, India

A copy of this form, together with a statement under 37 CFR 3.73(b) (Form PTO/SB/96 or equivalent) is required to be filed in each application in which this form is used. The statement under 37 CFR 3.73(b) may be completed by one of the practitioners appointed in this form if the appointed practitioner is authorized to act on behalf of the assignee, and must identify the application in which this Power of Attorney is to be filed.

**SIGNATURE of Assignee of Record**

The individual whose signature and title is supplied below is authorized to act on behalf of the assignee

Signature		Date	December 21, 2004
Name	Andrew J. Miller	Telephone	908-203-4949
Title	Board Designee		

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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**STATEMENT UNDER 37 CFR 3.73(b)**Applicant/Patent Owner: Rajender Kumar Potlapally et al.Application No./Patent No.: 10/507,399 Filed/Issue Date: September 13, 2004Entitled: NOVEL CRYSTALLINE FORM OF 5-[4-[[3-METHYL-4-OXO-3,4-DIHYDROQUINAZOLIN-2-YL] METHOXY]BENZYL]  
THIAZOLIDINE-2,4-DIONE POTASSIUM SALTDr. Reddy's Laboratories Limited, a Corporation

(Name of Assignee)

(Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is:

1. ☒ the assignee of the entire right, title, and interest; or
2. ☐ an assignee of less than the entire right, title and interest.  
The extent (by percentage) of its ownership interest is \_\_\_\_\_ %

in the patent application/patent identified above by virtue of either:

A ☒ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel \_\_\_\_\_, Frame \_\_\_\_\_, or for which a copy thereof is attached.

OR

B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as shown below:

1. From: \_\_\_\_\_ To: \_\_\_\_\_  
The document was recorded in the United States Patent and Trademark Office at  
Reel \_\_\_\_\_, Frame \_\_\_\_\_, or for which a copy thereof is attached.
2. From: \_\_\_\_\_ To: \_\_\_\_\_  
The document was recorded in the United States Patent and Trademark Office at  
Reel \_\_\_\_\_, Frame \_\_\_\_\_, or for which a copy thereof is attached.
3. From: \_\_\_\_\_ To: \_\_\_\_\_  
The document was recorded in the United States Patent and Trademark Office at  
Reel \_\_\_\_\_, Frame \_\_\_\_\_, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet.☒ Copies of assignments or other documents in the chain of title are attached.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, if the assignment is to be recorded in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

  
SignatureEDWARD D. PERGAMENT (Reg. No. 43,346)

Printed or Typed Name

Attorney for Dr. Reddy's Laboratories Limited

Title

June 10, 2005

Date

(908) 203-6500

Telephone Number

This collection of information is required by 37 CFR 3.73(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

## ASSIGNMENT

For good and valuable consideration that has been paid to us:

- (1) **Rajender Kumar Potlapally**
- (2) **Raju Srisilla**
- (3) **Ramabhadra Sarma Mamillapalli**
- (4) **Om Reddy Gaddam**

the assignors respectively having addresses at:

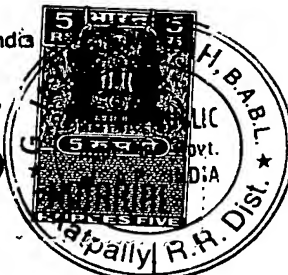
- (1) **Hyderabad, A.P., India**
- (2) **Hyderabad, A.P., India**
- (3) **Hyderabad, A.P., India**
- (4) **Hyderabad, A.P., India**

by: **DR. REDDY'S LABORATORIES LIMITED**, a corporation of India having its office at 7-1-27 Ameerpet, Hyderabad 500 016, Andhra Pradesh, India; (hereinafter called "**ASSIGNEE**"), we each do hereby sell, assign, and transfer to said **ASSIGNEE** our entire right, title, and interest in all countries of the world in and to any and all of our inventions and discoveries described and/or claimed in the patent application titled **NOVEL CRYSTALLINE FORM OF 5-[4-[3-METHYL-4-OXO-3,4-DIHYDROQUINAZOLIN-2-YL]METHOXY]BENZYL]THIAZOLIDONE-2,4-DIONE POTASSIUM SALT** and officially identified as: PCT International Application No. **PCT/IB03/00935** filed on **March 14, 2003**; in and to the right to file patent applications, utility model applications, and design registration applications in the name of **ASSIGNEE**, its designee, or in any or all of our names, at its election, on the aforesaid inventions and discoveries in all countries of the world, together with all rights of priority in the aforesaid countries deriving from the above-identified patent application under the International Convention for the Protection of Industrial Property, under the Inter-American Convention relating to Inventions, Patents, Designs and Industrial Models, and under any other international arrangement to which the United States now is or hereafter becomes a signatory, in and to any and all patents, utility models, and design registrations that are granted from any of the aforesaid applications, and in and to any continuing applications, reissues, renewals, and extensions therefrom, the same to be held and enjoyed by said **ASSIGNEE**, its successors, assigns, and other legal representatives to the full ends of the terms which may be granted, as fully and entirely as the same would have been held and enjoyed by us if this assignment and sale had not been made.

And we hereby individually covenant and agree that we will at any time, upon the request and at the expense of **ASSIGNEE** or its successors, assigns, or other legal representatives, execute and deliver any and all documents that may be necessary or useful to perfect the title of **ASSIGNEE**, or its successors, assigns, or other legal representatives, to the foregoing inventions and discoveries, patent, utility model, and design applications, and patents, industrial models, and designs, and continuations, divisions, reissues, renewals, and extensions thereof, including the execution and procurement of any and all further documents evidencing this assignment and sale as

may be necessary or desirable for recording the same in the patent offices of any country concerned, and that we will, at any time, upon the request and at the expense of **ASSIGNEE**, execute any additional or continuing applications for patents, utility models, and design registrations for said inventions and discoveries, or any part or parts thereof, and applications for patents of confirmation, registration, and importation based on rights granted from said additional or continuing applications, and reissues, renewals, and extensions therefor, and will make all rightful oaths and declarations and do all lawful acts that are reasonably necessary or useful for procuring or enforcing rights to the same, or for aiding therein, without further compensation.

<p>Executed this <u>22</u> day of <u>March</u>, 20<u>05</u>.</p> <p><u>P. Rajender Kumar</u> <b>Rajender Kumar Potlapally</b></p>	<p>Subscribed and sworn to before me this <u>22</u> day of <u>March</u>, 20<u>05</u> at <u>Hyderabad, INDIA</u>.</p> <p><u>G. Jayaramaiah</u> Notary Public <u>22.3.05</u></p> <p><u>G. JAYARAMAIAH, B.A.B.L.</u> (Printed name) &amp; NOTARY Appointed by Govt. of Andhra Pradesh, India Flat No.101, Balaji Villa, A.S.Raju Nagar, Kukatpally, R.R.Dist., HYDERABAD. My Commission Expires on 1st June 2007</p> <p>(Seal)</p> <p>Commission expires: _____</p>
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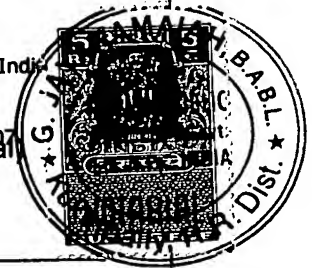


Executed this <u>22</u> day of <u>March</u> , 20 <u>05</u> .	Subscribed and sworn to before me this <u>22</u> day of <u>March</u> , 20 <u>05</u> at <u>Hyderabad, INDIA</u> .
<u>S. Dax</u> Raju Srisilla	<u>G. Jayaramaiah</u> Notary Public (Printed name) <b>G. JAYARAMAIAH, B.A.B.L.</b> ADVOCATE & NOTARY Appointed by Govt. of Andhra Pradesh, India Flat No.101, Balaji Villa, A.S.Raju Nagar, Kukatpally, R.R.Dist., HYDERABAD. My Commission Expires on 1st June 2007 (Seal)
	Commission expires: _____

Executed this <u>22<sup>nd</sup></u> day of <u>March</u> , 20 <u>05</u> .	Subscribed and sworn to before me this <u>22</u> day of <u>March</u> , 20 <u>05</u> at <u>Hyderabad, INDIA</u> .
<u>K.C.R. Sarma</u> Ramabhadra Sarma Mamillapalli	Notary Public <u>G. Jayaramaiah</u> (Printed name) <b>G. JAYARAMAIAH, B.A.B.L.</b> ADVOCATE & NOTARY Appointed by Govt. of Andhra Pradesh, India Flat No.101, Balaji Villa, A.S.Raju Nagar, Kukatpally, R.R.Dist., HYDERABAD. My Commission Expires on 1st June 2007 (Seal)
	Commission expires: _____

BEST AVAILABLE COPY

<p>Executed this <u>29<sup>th</sup></u> day of <u>March</u>, 2005.</p> <p><i>Om Reddy</i></p> <p><u>Om Reddy Gaddam</u></p>	<p>Subscribed and sworn to before me this <u>29<sup>th</sup></u> day of <u>March</u>, 2005 at <u>HYDERABAD, INDIA</u></p> <p><u>G. Jayaramaiah</u> Notary Public</p> <p>(Printed name) <b>G. JAYARAMAIAH, B.A.B.L</b> <b>ADVOCATE &amp; NOTARY</b> Appointed by Govt. of Andhra Pradesh, India Flat No.101, Balaji Villa, A.S.Raju Nagar, Kukatpally, R.R.Dist., HYDERABAD. My Commission Expires on 1st June 2007 (Seal)</p> <p>Commission expires: _____</p>
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